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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. ELIZABETH HOLMES and RAMESH "SUNNY" BALWANI, Defendants.	CASE NO. 18-CR-00258 EJD **UNITED STATES' OPPOSITION TO DEFENDANTS' MOTION TO COMPEL** Date: June 28, 2019 Time: 10:00 a.m. Court: Hon Edward J. Davila

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I. INTRODUCTION

The Court should deny Defendant's motion to compel because none of the materials covered by the motion are in the possession of the prosecution. Instead, the materials are held by other government agencies, such that any production or disclosure is at those agencies' discretion. Rather than avail themselves of Federal Rule of Criminal Procedure 17 to request these documents directly from the custodian agencies, Defendants seek the Court's assistance in forcing the prosecution to go beyond its discovery obligations and do Defendants' investigatory work for them. Defendants' arguments suffer from serious flaws.

For example, Defendants ask the Court to treat the federal government as a monolith and assume that every government agency has automatic access to the documents of every other. In reality, the federal government is comprised of numerous agencies and components, each of which has its own independent mission and a significant degree of autonomy over its records and resources. Defendants claim that the prosecution somehow hand-picked documents from agencies like FDA and CMS during earlier stages of its investigation, selecting materials favorable to its case and leaving behind exculpatory evidence. In fact, the prosecution merely tailored its requests to these agencies to capture the documents most relevant to this case without imposing undue burden on those agencies. Defendants demand that the government produce documents on the grounds that those documents are favorable and material to the defense, but their arguments on these points are speculative. Ignoring the work product doctrine, Defendants' requested documents also encompass internal communications and notes constituting the work product of an agency engaged in ongoing litigation against Balwani. If granted, Defendants' motion threatens to impermissibly expand the government's discovery obligations and make the prosecution responsible for the document productions of third parties over which it has no control. The Court should avoid this unfair result.

The simplest reason to deny Defendants' motion, however, is that it largely seeks relief that the prosecution has already provided. Before Defendants filed their motion to compel, the government offered to use its best efforts to obtain and produce the documents covered by the motion. Although Defendants rejected that offer, the government nonetheless submitted written requests to the custodian agencies and has recently learned that, subject to reasonable conditions, the agencies are willing to

produce the majority of the requested documents. The government has also offered to make case agent interview notes available for Defendants' inspection, and to seek to review SEC's interview notes for *Brady* material—accommodations that will sufficiently protect Defendants' rights. A court order is not necessary where it would do nothing more than restate the government's discovery obligations or compel action the government has already taken.

II. FACTUAL & PROCEDURAL BACKGROUND

A. Defendants' Fraud and the Pending Criminal Charges

In this case, Defendants' fraudulent conduct took place over several years and resulted in hundreds of millions of dollars lost by investor victims as well as the defrauding of doctors and patients who believed Defendants' representations that Theranos's tests were accurate and reliable. The Superseding Indictment (Dkt. No. 39) alleges schemes to defraud the above groups of victims, and specifies misrepresentations Defendants made in furtherance of those schemes. For example, the Indictment alleges that Defendants claimed Theranos's proprietary analyzer was capable of performing the full range of clinical tests using small blood samples drawn from a finger stick and producing results more accurate and reliable than those yielded by conventional methods, when Defendants knew the company's proprietary analyzer had far more limited abilities. The Indictment similarly alleges that Defendants made false or misleading statements on subjects like Theranos's financial health, Theranos's partnership with Walgreens, Theranos's business with the United States Department of Defense, the purported validation of Theranos devices by pharmaceutical companies and research institutions, and the FDA approval status of Theranos's analyzer and tests. Contrary to Defendants' claims, the government's case does not rest solely on evidence from FDA and CMS. Indeed, Defendants' repeated misrepresentation concerning FDA was just one of many underlying their scheme to defraud.

B. The Prosecution's Document Production to Date

Over the course of its investigation in this matter, the government has collected millions of pages of evidence from numerous sources, including: (1) investor victims who parted with substantial sums of money based on false information from Defendants; (2) doctor and patient victims who purchased and relied on Theranos's tests based on false information about the accuracy of those tests; (3) Theranos itself and former employees of the company; (4) other corporate and academic entities that explored

partnerships with Theranos; and (5) components of the federal government that interacted with Theranos as part of their regulatory responsibilities or other missions.

The government has already produced the vast majority of all of the materials that it has obtained from the sources above, and is preparing to produce the rest. As part of its production, the government provided to the defense approximately 300,000 pages of documents collected from FDA and Centers for Medicare and Medicaid Services (CMS). The government obtained those documents pursuant to requests targeting materials relevant to Theranos whether the evidence was inculpatory or exculpatory. (See, e.g., Wade Decl. Exhs. 6 & 8). In total, the government's production to date includes more than twenty million pages of documents. As the government collects additional materials in connection with its ongoing investigation, it will continue to provide those documents to the defense in a timely manner.

C. Defendant Balwani's Previous Attempts to Obtain Additional Agency Documents

The pending motion does not represent Defendants' first attempt to obtain the requested documents from the agencies. Months before joining the instant motion, Balwani served civil subpoenas on FDA and CMS, seeking documents in numerous broad categories encompassing internal agency materials and correspondence with other agencies, legislators, journalists, entities in the healthcare industry, and other laboratories. The government understands that counsel for Balwani subsequently engaged in a lengthy meet and confer process with counsel for FDA and CMS. Although that process revealed significant disagreements over the proper scope of the subpoenas, Balwani has not moved to compel production under those subpoenas. As an alternative means to obtaining these documents, Defendants have now demanded that the prosecution retrieve them from the custodian agencies and produce them.

Despite their ability to issue subpoenas under Rule 17 of the Federal Rules of Criminal Procedure compelling third parties to disclose relevant evidence, neither Defendant has issued a subpoena in the criminal case to any of the federal agencies addressed in their motion.

D. The Prosecution's Good-Faith Efforts to Obtain the Requested Materials

In late March 2019, defense counsel sent a letter asking the government to obtain and produce additional materials from several government agencies, including FDA, CMS, SEC, Department of Health and Human Services (DHHS), and Department of Defense (DOD). (Wade Decl. Exh. 5, pp. 8-

10).

In early April 2019, the government met and conferred with defense counsel regarding the defense's requests for additional documents from FDA, CMS, and DOD. Following the initial discussion with the defense, the prosecution contacted counsel for FDA, CMS, and DOD in order to inquire about the agencies' ability and willingness to produce additional documents in this case. During those conversations, government counsel confirmed its understanding that the prosecution did not have access to the requested documents held by these agencies.

For example, more than one agency raised concerns regarding the large volume of documents previously provided to the prosecution earlier in its investigation of this case, with agency representatives understandably wary of expending agency resources on additional broad document requests that overlapped with those earlier productions. That drain on resources was compounded by technical limitations facing the agencies. CMS, for instance, noted that it did not have access to document database software, and was relying on DOJ's Litigation Technology Service Center to host documents being collected in response to Balwani's civil subpoena. At least one agency also informed government counsel that applicable law might limit its discretion to disclose additional documents post-Indictment, since the case did not involve charges under certain statutes relevant to the agency's purview. The agencies also explained their obligations to protect confidential documents held in connection with their sensitive missions as regulatory and defense organizations. In some cases, those responsibilities would require the agencies to make the sharing of documents conditional on the prosecution's promise not to disclose that sensitive information further absent agency permission. The agencies recognized that such a condition would be problematic given the government's discovery obligations and general practice of producing such evidence directly to the defense. In that same vein, agency representatives discussed the need for a waiver from the entity controlling Theranos's legal rights before they would be permitted to disclose sensitive information received from the company during its operation. Government counsel was informed that Balwani's counsel had agreed to obtain such a waiver at the beginning of 2019 but had not yet succeeded.

Shortly after receiving this information from the agencies, government counsel had another discussion with the defense. During that conversation, counsel for the government explained that it had

already produced the documents it received from FDA, CMS, and DOD and did not have access to materials still in the agencies' possession. Although not obligated to do so, the government offered to make good-faith efforts to obtain the documents requested by the defense. In connection with that offer, the government cautioned defense counsel that, because any additional production by FDA, CMS, or DOD would be at the agencies' discretion, the prosecution could not guarantee that it would be able to obtain and produce all agency documents responsive to Defendants' requests.[1] Despite the lack of such a guarantee, government counsel believed that it was worthwhile to seek the requested documents from the agencies, and asked the defense to hold off on filing a motion to compel so that process could play out. Defense counsel rejected this offer immediately and indicated that they planned to proceed with the instant motion.

After Defendants filed their motion, government counsel continued to confer with representatives for FDA and CMS. The government's discussions with the two agencies yielded information regarding the appropriate format of any additional document requests and the contact information of the individuals best situated to respond to such requests.

On May 9, 2019, the government sent letters to FDA and CMS formally requesting additional documents in connection with this case. (Bostic Decl. Exhs. A & B). In making those requests, the government adopted verbatim Defendants' descriptions of the requested documents. The government subsequently held follow-up discussions with FDA and CMS representatives to provide contextual information for the requests and to encourage a timely response.

E. The Agencies' Agreements to Produce Further Documents

On June 7, 2019, FDA responded to the prosecution's request for additional documents, agreeing to produce responsive materials. (Bostic Decl. Exh. C). In its letter, FDA addresses its earlier production of approximately 40,000 pages, and lays out its expectations regarding the categories of responsive documents likely remaining in its possession. The letter also reports that, in response to the subpoena it received from Balwani in the SEC action, it has already used relevant keywords to search

[1] Defendants' characterizations of information relayed by the government during this conversation are incomplete and misleading. The government contests these descriptions and has provided a more complete account of the agencies' concerns above.

the records of at least 45 custodians—including current and former FDA employees—and has collected more than 62,000 documents. FDA states that it is now in the process of reviewing those documents for responsiveness as well as for privileged or otherwise protected information. FDA agrees that, in connection with that ongoing review, it will produce to the government documents responsive to the six categories comprising the pending requests. Because the pending document requests did not include any time limitation, FDA intends to take the reasonable step of limiting its production to the eight-year time period covered by Balwani's broader subpoena in the SEC civil case.

Completing this production will require FDA to address and overcome several challenges. As noted in the letter, the agency does not have the ability to de-duplicate its newly collected documents against its previous productions or against the rest of the newly collected set, requiring manual comparison so as to avoid duplication of review effort. This process will presumably slow FDA's production somewhat and increase the already significant burden on the agency. Because the government's requests call for internal agency correspondence, FDA will need to locate and redact privileged information from its documents before production. FDA also is prohibited by statute from releasing trade secrets and confidential commercial information obtained through its regulatory authority. (*Id.* [citing 21 U.S.C. 331(j), 21 U.S.C. 360j(c), and 18 U.S.C. 1905]). Accordingly, the agency will review its production to remove or redact such information as necessary.[2] Despite these obstacles and the amount of resources it will take to address them, FDA estimates that it will be in a position to begin a rolling production of responsive documents within one month.

On June 10, 2019, CMS responded to the prosecution's document requests. (Bostic Decl. Exh. D). In its letter, CMS notes that it has already expended significant resources to collect and

[2] Although Defendants were formerly affiliated with Theranos, they both left the company before it ceased operations, and no longer have the authority to authorize FDA to release Theranos's trade secrets and confidential commercial information. Theranos itself previously provided a waiver that authorized FDA's previous productions. Upon its dissolution, Theranos entered into an assignment for the benefit of creditors, with the assignee now holding Theranos's rights and assets. The Theranos assignee has not given a waiver allowing FDA to produce confidential information in the recently requested documents. The government understands that Balwani's counsel was recently able to negotiate such a waiver from the assignee permitting FDA and CMS to release confidential Theranos information in response to the subpoena in the SEC case. (Bostic Decl. Exh. F). If defense counsel is able to secure a similar waiver for the criminal case, the FDA may be able to produce additional documents and at a faster pace, thought it will still need to capture and redact third-party confidential information from its production.

produce more than 260,000 pages of documents to DOJ in this case, and correctly points out that the government's latest document requests overlap with that earlier production. Like FDA, CMS reports that it has already begun preparing a production of documents in response to Balwani's subpoena in the SEC action, and will produce those materials—including documents responsive to the six categories in the government's request—in the criminal case as well. Based on CMS's knowledge of its files, its letter summarizes what it has already produced and previews what it is likely to have remaining with respect to responsive documents. Except for one category for which CMS has no responsive documents, CMS agrees to retrieve and produce external and/or internal documents pursuant to the government's request to the extent such documents have not already been produced.

CMS's production will require the agency to devote substantial resources to the collection and review of potentially responsive documents. Additionally, because some of the documents responsive to the government's requests are internal agency communications and other sensitive items, they implicate CMS's interest in protecting the confidentiality of those materials. Accordingly, CMS asks that the Court enter a protective order that will shield these documents from misuse and unnecessary public disclosure. The government supports CMS's request for a protective order and, to facilitate production, will work with the defense to prepare an appropriate proposed order for the Court's consideration.

Along with CMS's response letter, the government received a declaration from a representative of the California Department of Public Health's (CDPH) Laboratory Field Services. (Bostic Decl. Exh. E). On behalf of CDPH, that declaration affirms that CDPH had only a small number of CMS documents relevant to the 2013 CLIA survey of Theranos, which CMS will produce. CDPH is currently not aware of any communications, either internally or with CMS, regarding the 2013 survey, but has begun an email search to verify that no such communications exist.

Although the prosecution is unable to control the collection and production efforts of the above agencies, it will continue to work toward obtaining the requested documents from the agencies in order to produce those materials to the defense.

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III. ARGUMENT

A. Defendants' motion seeks documents not in the prosecution's possession, custody, or control.

The discovery record shows that the government has taken a broad view to discovery, exceeding its discovery obligations in producing documents in its possession. As described above, the government has collected tens of millions of pages of evidence in this case. Its treatment of those documents shows that the government is not motivated by a desire to deprive the defense of information or provide the bare minimum. On the contrary, the government has produced the vast majority of the collected materials to both Defendants without engaging in the lengthy review that would be necessary to determine that each of those documents is discoverable under Rule 16, *Brady*, or on some other basis. Consistent with that practice—and despite the defense's rejection of the offer—the government continues its work to obtain and produce the documents Defendants are requesting. Those documents remain outstanding only because, at this time, the government does not possess the documents in order to produce them.

Defendants lean heavily on the fact that the government previously requested and obtained documents from FDA and CMS, but this fact cannot be dispositive. It would be problematic if a single, voluntary production of documents by a third party were sufficient to give the prosecution "access" to the rest of that party's documents. Under such a system, defendants could obtain unfettered access to victims' documents through the government, and third parties might hesitate to share any evidence with criminal investigators.

In this case specifically, the facts belie Defendants' claim that FDA and CMS previously gave the prosecution "carte blanche" access to agency documents. When those agencies shared documents with the government earlier in the criminal investigation, that access was not unlimited. Indeed, FDA's letter in response to the prosecution's March 2017 request expressly states that the authorization being provided by the agency "does not extend to trade secret information, disclosure of which outside the Department of Health and Human Services is prohibited by law [cite], or to other information disclosure of which is otherwise prohibited by law or regulation." (Wade Decl. Exh. 7, p.2). That same letter goes on to remind the prosecution that "FDA's responsive information and records that are exempt from

disclosure to the public shall not be further disclosed to other personnel outside of [the prosecution's] office without FDA's written permission." (*Id.*).

The government's supposed access to agency documents is especially tenuous with respect to CMS. Defendants' motion describes contact between CMS and Theranos, but fails to show meaningful contact with the prosecution supporting their claim of access. *See United States v. Salyer*, 271 F.R.D. 148, 157 (E.D. Cal. 2010) (denying discovery where "such informal contacts [with the government] have not risen to the level where the United States Trustee would be considered the 'government' in the criminal matter"). In sharp contrast to cases where disclosure was ordered, there is no serious argument here that CMS participated in the criminal investigation of Theranos or Defendants. *Cf. United States v. W.R. Grace*, 401 F. Supp. 2d 1069, 1082 (D. Mont. 2005) (requiring prosecution to produce documents held by EPA where DOJ and EPA had investigated jointly). Nor is CMS—or FDA, for that matter—as closely tied to the United States Attorney's Office as are fellow Department of Justice components the FBI and the Bureau of Prisons. *Cf. United States v. Zuno-Arce*, 44 F.3d 1420, 1427 (9th Cir. 1995) (prosecution deemed to be in possession of FBI files); *United States v. Santiago*, 46 F.3d 885, 893-94 (9th Cir. 1995) (prosecution had access to BOP files).

The primary case Holmes relies on, *United States v. Bryan*, 868 F.2d 1032 (9th Cir. 1989), is distinguishable. That case involved tax and wire fraud charges arising from a nationwide investigation of Bryan's activities coordinated by the national office of the IRS. In *Bryan*, The Ninth Circuit rejected the government's argument that Rule 16 or *Brady* extended only to evidence in the District of Oregon, where the prosecution was brought. *Id*. at 1036-1037. Here, by contrast, CMS had no involvement in managing, directing, or executing the criminal investigation, neither the SEC nor the DOJ exercised such authority over each other, and only the FDA-CI office participated in the criminal investigation. *See also United States v. Stever*, 603 F.3d 747, 752 (9th Cir. 2010) (government conceded possession of documents within Rule 16 request).

Because Defendants have not shown that the government actually has access to the FDA and CMS documents described in its motion, the Court should not compel the government to produce these materials. Instead, the Court should allow the government to continue its efforts to obtain and produce these documents voluntarily. As described above, FDA and CMS have offered reasonable responses to

the requests for additional documents. Should Defendants wish to contest those responses, a Rule 17 subpoena is a more appropriate vehicle than the instant motion.

B. The defense's arguments regarding the content and materiality of the requested documents are speculative.

Even if Defendants could convince the Court that the government has control over these agency documents, they still could not meet their burden to establish that the documents are material under the applicable rules. To obtain discovery under Rule 16, a defendant must make a prima facie showing of materiality. *United States v. Little*, 753 F.2d 1420, 1445 (9th Cir.1984); *see also United States v. Cadet*, 727 F.2d 1453, 1468 (9th Cir.1984) (same). A general description of the information sought will not suffice, nor will conclusory allegations of materiality. Rather, Defendants must present facts showing that the government is in possession of information helpful to the defense. *See Little*, 753 F.2d at 1445; *Cadet*, 727 F.2d at 1466–68; *United States v. Mandel*, 914 F.2d 1215, 1219 (9th Cir.1990); *United States v. Muniz–Jaquez*, 718 F.3d 1180, 1183 (9th Cir.2013); *United States v. Zone*, 403 F.3d 1101, 1107 (9th Cir.2005).

In this case, the defense relies on assumptions to describe the favorable evidence that may be in the possession of FDA and CMS. For example, Defendants assume that the agencies must possess additional communications with the journalist whose October 2015 article brought attention to the fraud at Theranos, and further assume that those communications will show bias on the part of the agencies. Defendants have failed, however, to present any evidence of actual bias or undue influence in connection with the agencies' interactions with Carreyrou or any other member of the media. The same is true with respect to the agencies' contacts with competing laboratories. And even if Defendants could show that this evidence is likely to exist as they describe, they still could not show materiality under Rule 16. The Supreme Court has advised that Rule 16 applies primarily to evidence relevant to the government's case in chief. *United States v. Armstrong*, 517 U.S. 456, 462 (1996). In *Armstrong*, the Supreme Court held that the defense was not entitled to discovery to prove a selective-prosecution claim because it "is not a defense on the merits of the criminal charge" and "asks a court to exercise judicial power over a 'special province of the Executive.'" *Id.* at 464. Similarly, here, Defendants' speculative bias theory regarding FDA and CMS is too far afield from the subject matter of the government's case in

chief. Insofar as the case in chief involves FDA, it relates to *what Defendants' knew* and *what FDA told them* with respect to approval requirements. The agency's underlying motives are beside the point—and Defendants have provided no real reason to question them. As the court in *Armstrong* reasoned, "the showing necessary to obtain discovery should itself be a significant barrier to the litigation of insubstantial claims." *Id.*

Moreover, as set forth in FDA's and CMS's response letters, Defendants' document requests are broad and burdensome. The agencies will be required to expend substantial resources in order to locate, review, and produce responsive materials. Under these circumstances, courts apply extra scrutiny to the question of materiality, and deny motions to compel where the documents in question would be unduly burdensome to produce. *See Mandel*, 914 F.2d at 1219; *Cadet*, 727 F.2d at 1468 (discovery request was so far ranging and potentially burdensome that it was an abuse of discretion to grant). Defendants' overbroad and speculative requests cannot survive scrutiny under this standard. Accordingly, the Court should deny Defendants' motion and permit FDA and CMS to make a reasonable document production in response to the pending requests made voluntarily by the government.

C. The government has no obligation to obtain and produce documents held by state agencies not involved in the criminal investigation.

Even if Defendants could make the showing necessary to compel the prosecution to obtain discovery from the federal agencies named in their motion, the law is clear that this same reasoning would not apply to documents held in the possession of state agencies.

In *United States v. Fort*, 478 F.3d 1099 (9th Cir.2007), the Ninth Circuit held that the government is not deemed "to have knowledge or access to anything generated by a state or local actor that is not actually known by and in the possession of the prosecutor." *Id.* at 1100. Citing an earlier decision, the Ninth Circuit in that case confirmed that the opinion "establishes no principle of constructive possession" in this context. *Id.*; *see also United States v. Chavez–Vernaza*, 844 F.2d 1368, 1375 (9th Cir.1988) ("[T]he federal government had no duty to obtain from state officials documents of which it was aware but over which it had no actual control."); *United States v. Gatto*, 763 F.2d 1040 (9th Cir. 1985) (evidence found and held by state authorities became discoverable only when federal authorities gained physical possession; "the triggering requirement under Rule 16(a)(1)(E) is that the…

tangible objects be in the actual possession… of the government"). Simply put, the government "is not obligated to review state law enforcement files not within its possession or control." *United States v. Dominguez–Villa*, 954 F.2d 562, 566 (9th Cir.1992). These principles defeat Defendants' claim as to all documents in the custody of the California Department of Public Health. That CMS has nonetheless agreed to produce responsive documents from CDPH merely underscores the fact that a court order compelling this production is unnecessary.

D. The government has already produced discoverable materials received from SEC.

While the prosecution and its case agents have conducted an investigation of the criminal fraud that occurred at Theranos, SEC has conducted its own, parallel investigation into attendant violations of securities laws by these same Defendants. Although the investigations were independent, driven by different aims and governed by different standards, the prosecution and SEC coordinated aspects of their investigations for the sake of efficiency. The primary benefit of this coordination was to reduce the burden on third-party witnesses and document custodians common to the two investigations. Witnesses who would otherwise sit for separate interviews with the prosecution and SEC experienced less inconvenience through that coordination. Similarly, document custodians who might otherwise be required to produce Theranos-related documents to the prosecution and SEC independently saved time and expense to the extent documents were shared between the criminal and civil investigations. The government has produced to the defense all of the discovery documents shared by the SEC, along with reports in the government's possession memorializing witness interviews conducted by the prosecution and SEC. Defendants claim to be dissatisfied with this disclosure, and now seek to compel the prosecution to produce notes and other documents held by the SEC. This request from the defense is unreasonable in light of the fact that the government does not have possession, custody, or control over the SEC's notes and other internal documents. Moreover, those documents clearly represent the attorney work product of counsel for an entity currently in active litigation against one of the Defendants. Defendants' argument also ignores that such documents are not discoverable under the Federal Rules of Criminal Procedure, which state that the Rule 16:

> … does not authorize the discovery or inspection of reports, memoranda, or other internal government documents made by an attorney for the government or other

> government agent in connection with investigating or prosecuting the case. Nor does this rule authorize the discovery or inspection of statements made by prospective government witnesses except as provided in 18 U.S.C. § 3500.

Fed. R. Crim. P. 16(a)(2).

In addition to Rule 16's limits, the Dodd-Frank Act makes it clear that the SEC does not waive its work product and other privileges by sharing information with DOJ. *See* 15 U.S.C. § 78x(f)(1)(A) ("The [SEC] shall not be deemed to have waived any privilege applicable to any information by transferring that information to or permitting that information to be used by any agency . . . .") & 18 U.S.C. § 6 (defining agency to include any department of the United States).

Despite the principles above, the government will seek to review SEC's witness interview notes for *Brady* material. This measure exceeds the government's obligations and should be more than sufficient to protect Defendants' interests. Accordingly, the Court should deny Defendants' motion, and Defendants must settle for what the law entitles them to—namely, the discoverable evidence in this case. *See SEC v. Reyes*, No. C 06-04435 CRB, 2007 WL 528718, at *4 (N.D. Cal. Feb. 13, 2007) ("Defendant Reyes may be entitled to all exculpatory evidence, but he cites no authority for the proposition that he is entitled to have any document revealing what attorneys at the SEC or DOJ *think* about such evidence"); *see also United States v. Tealer*, 2015 U.S. Dist. LEXIS 157954, at *2 (D. Neb. Nov. 23, 2015) (denying *Brady* request for internal documents, as "Defendant has pointed to no authority supporting the proposition that *Brady* requires the production of internal government documents which simply discuss evidence").

E. An order requiring the government to comply with its discovery obligations is unnecessary and impracticable.

Several of Defendants' arguments ask the Court to compel the government to abide by discovery obligations that the government already intends to fulfill. As to those arguments, the Court should decline to issue such a superfluous order, consistent with the case law discussing these discovery obligations. At the same time, however, several of Defendants' demands go well beyond what the law requires of the government, and the Court should decline to issue Defendants' proposed order on that basis as well. Both of these problems infect Defendants' request for reports, notes, correspondence, and

other materials regarding communications with witnesses.

The government's *Brady* obligation is a "self-executing responsibility on the part of the prosecutor.... [T]here is no need for a court order to require compliance with *Brady*." *United States v. Flores*, No. 08–0730–WHA, 2011 WL 1100137, at *1 (N.D.Cal. Mar. 24, 2011); *see also United States v. Lucas*, 841 F.3d 796, 807 (9th Cir. 2016) ("it is the government, not the defendant or the trial court, that decides *prospectively* what information, if any, is material and must be disclosed under *Brady*"; "*Brady* does not permit a defendant to sift through information held by the government to determine materiality."); *see also United States v. Jennings*, 960 F.2d 1488, 1491–92 (9th Cir.1992) (admonishing courts to avoid interfering with executive branch's *Brady* obligations unless there is "a clear basis in law or fact to believe that [interference is] necessary....").

In this case, the government has consistently produced to the defense FBI 302s and other similar investigatory reports memorializing relevant information provided to the government during witness interviews. The government will continue to abide by this practice, and there is no need for the Court to mandate it. To address Defendants' stated concerns regarding *Brady* material in this context, the government has agreed to make available to the defense agent notes of witness interviews, so that the defense can conduct its own review and confirm the absence of any material inconsistencies. This step exceeds the government's discovery obligations under the standards discussed above, especially in light of the fact that such notes are expressly not discoverable under Federal Rule of Criminal Procedure 16(a)(2), quoted above.

/ /

IV. CONCLUSION

The relief sought by Defendants in the instant motion is unnecessary and improper. For the foregoing reasons, the Court should deny Defendants' motion to compel in its entirety.

DATED: June 12, 2019

Respectfully submitted,

ADAM A. REEVES
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Acting Under Authority Conferred
by 28 U.S.C. § 515

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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. ELIZABETH HOLMES and RAMESH "SUNNY" BALWANI, Defendants.	CASE NO. 18-CR-00258 EJD **DECLARATION OF JOHN BOSTIC IN OPPOSITION TO DEFENDANTS' MOTION TO COMPEL** Date: June 28, 2019 Time: 10:00 a.m. Court: Hon Edward J. Davila

I, JOHN BOSTIC, declare as follows:

1. I am an Assistant United States Attorney, representing the United States in the above-captioned matter. I am admitted to practice before this Court. I hereby attest to the following facts.

2. Attached hereto as **Exhibit A** is a true a correct copy of a May 9, 2019 letter sent by government counsel to FDA in connection with this case.

3. Attached hereto as **Exhibit B** is a true a correct copy of a May 9, 2019 letter sent by government counsel to CMS in connection with this case.

4. Attached hereto as **Exhibit C** is a true a correct copy of a June 7, 2019 letter received by government counsel from FDA in response to the document requests in Exhibit A.

5. Attached hereto as **Exhibit D** is a true a correct copy of a June 10, 2019 letter received by government counsel from CMS in response to the document requests in Exhibit B.

6. Attached hereto as **Exhibit E** is a true a correct copy of a June 3, 2019 Declaration from a representative of California Department of Public Health provided to the government along with CMS's responsive letter, Exhibit D.

7. Attached hereto as **Exhibit F** is a true a correct copy of a June 11, 2019 letter from the Theranos assignee providing a waiver authorizing FDA and CMS to produce confidential Theranos information in the SEC civil case.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct to the best of my knowledge.

Executed this 12th day of June, 2019.

__/S/_____
JOHN C. BOSTIC
Assistant United States Attorney

EXHIBIT A

United States Attorney
Northern District of California

150 Almaden Boulevard, Suite 900
San Jose, California 95113

(408) 535-5061
FAX:(408) 535-5066

May 9, 2019

VIA EMAIL AND FEDERAL EXPRESS

Lauren DiPaola
Lead Testimony Specialist
Division of Information Disclosure Policy
Office of Strategic Planning and Operational Policy
U.S. Food and Drug Administration
Office of Regulatory Affairs (ORA)
12420 Parklawn Drive
Element Bldg., Rm. 4042
Rockville, Maryland 20857
lauren.dipaola@fda.hhs.gov

Re: Document Access Request –
United States v. Elizabeth Holmes and Ramesh Balwani, 18-CR-00258 EJD

Dr. Ms. DiPaola:

Federal criminal charges have been filed against Elizabeth Holmes and Ramesh Balwani, and that prosecution is currently pending under case number 18-CR-00258 EJD in the Northern District of California.

In connection with this prosecution, Defendants have requested certain categories of documents that may have been created or compiled by the U.S. Food and Drug Administration. The United States Attorney's Office already has produced to Defendants documents previously obtained from the FDA, but recognizes that there may be additional materials responsive to Defendants' requests in the possession of the FDA to which my office does not have access.

Accordingly, the United States Attorney's Office hereby requests access to the following documents and information in connection with the above-referenced case, to the extent such documents are within the FDA's possession:

1. Any and all correspondence or communications regarding Theranos between the federal government and John Carreyrou, The Wall Street Journal, or their employees,

agents, or counsel, and all government documents, communications, correspondence, notes, or recordings (including intra-agency and/or inter-agency correspondence) regarding same;

2. Any and all government documents, communications, correspondence, notes, or recordings (including intra-agency and/or inter-agency communications) regarding Theranos' Clinical Laboratory Improvement Amendments ("CLIA") compliance during the time period of the charged conspiracies, including but not limited to those that concern the 2015 CLIA survey of Theranos;

3. Any and all correspondence or communications regarding Theranos between the government and any clinical laboratory company or association affiliated with clinical laboratories (including but not limited to LabCorp, Quest Diagnostics, and the American Clinical Lab Association), or their employees, agents, or counsel, and all government documents, communications, correspondence, notes, or recordings (including intra-agency and/or inter-agency correspondence) regarding same;

4. Any and all government documents, communications, correspondence, notes, or recordings (including intra-agency and/or inter-agency communications) regarding the FDA's determination of the type of FDA approval required for Theranos' proprietary technology;

5. Any and all FBI 302s or other agency ROIs memorializing government communications with witnesses, and all government documents, communications, correspondence, notes, or recordings (including intra-agency and/or inter-agency correspondence) regarding same; and

6. Any and all government documents, communications, correspondence, notes, or recordings (including intra-agency and/or inter-agency communications) regarding the 2013 CLIA survey of Theranos.

Please write back at your earliest convenience to convey the FDA's response to the above requests. Feel free to contact me by telephone at any time should you have any questions regarding this matter.

Very truly yours,

ADAM A. REEVES
Attorney for the United States
Acting Under Authority Conferred
by 28 U.S.C. § 515

/s/
JOHN C. BOSTIC
Assistant United States Attorney

EXHIBIT B

United States Attorney
Northern District of California

150 Almaden Boulevard, Suite 900
San Jose, California 95113

(408) 535-5061
FAX:(408) 535-5066

May 9, 2019

VIA FEDERAL EXPRESS

Karen W. Dyer MT(ASCP), DLM
Director, Division of Clinical Laboratory Improvement and Quality
Centers for Medicare & Medicaid Services
7500 Security Blvd.
Baltimore, Maryland 21244

Re: Document Access Request –
United States v. Elizabeth Holmes and Ramesh Balwani, 18-CR-00258 EJD

Dr. Ms. Dyer:

Federal criminal charges have been filed against Elizabeth Holmes and Ramesh Balwani, and that prosecution is currently pending under case number 18-CR-00258 EJD in the Northern District of California.

In connection with this prosecution, Defendants have requested certain categories of documents that may have been created or compiled by the U.S. Centers for Medicare & Medicaid Services. The United States Attorney's Office already has produced to Defendants documents previously obtained from CMS, but recognizes that there may be additional materials responsive to Defendants' requests in the possession of CMS to which my office does not have access.

Accordingly, the United States Attorney's Office hereby requests access to the following documents and information in connection with the above-referenced case, to the extent such documents are within CMS's possession:

1. Any and all correspondence or communications regarding Theranos between the federal government and John Carreyrou, The Wall Street Journal, or their employees, agents, or counsel, and all government documents, communications, correspondence, notes, or recordings (including intra-agency and/or inter-agency correspondence) regarding same;

2. Any and all government documents, communications, correspondence, notes, or recordings (including intra-agency and/or inter-agency communications) regarding Theranos' Clinical Laboratory Improvement Amendments ("CLIA") compliance during the time period of the charged conspiracies, including but not limited to those that concern the 2015 CLIA survey of Theranos;

3. Any and all correspondence or communications regarding Theranos between the government and any clinical laboratory company or association affiliated with clinical laboratories (including but not limited to LabCorp, Quest Diagnostics, and the American Clinical Lab Association), or their employees, agents, or counsel, and all government documents, communications, correspondence, notes, or recordings (including intra-agency and/or inter-agency correspondence) regarding same;

4. Any and all government documents, communications, correspondence, notes, or recordings (including intra-agency and/or inter-agency communications) regarding the FDA's determination of the type of FDA approval required for Theranos' proprietary technology;

5. Any and all FBI 302s or other agency ROIs memorializing government communications with witnesses, and all government documents, communications, correspondence, notes, or recordings (including intra-agency and/or inter-agency correspondence) regarding same; and

6. Any and all government documents, communications, correspondence, notes, or recordings (including intra-agency and/or inter-agency communications) regarding the 2013 CLIA survey of Theranos.

Please write back at your earliest convenience to convey CMS's response to the above requests. Feel free to contact me by telephone at any time should you have any questions regarding this matter.

Very truly yours,

ADAM A. REEVES
Attorney for the United States
Acting Under Authority Conferred
by 28 U.S.C. § 515

/s/
JOHN C. BOSTIC
Assistant United States Attorney

CC (via email): Lindsay Turner, HHS/OGC

EXHIBIT C

U.S. FOOD & DRUG ADMINISTRATION

Office of the Chief Counsel
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

June 7, 2019

Via Email

John C. Bostic
Assistant United States Attorney
U.S. Attorney's Office
Heritage Bank Building
150 Almaden Blvd. Suite 900
San Jose, CA 95113

Re: Document Access Request – *United States v. Elizabeth Holmes & Ramesh Balwani*, 18-CR-00258 EJD (N.D. Cal.)

Dear Mr. Bostic:

This letter responds to your letter dated May 9, 2019, addressed to Lauren DiPaola, Lead Testimony Specialist at the U.S. Food and Drug Administration ("FDA"), which seeks documents and information in FDA's possession in response to requests made by the Defendants in the above-referenced action, Elizabeth Holmes ("Holmes") and Ramesh Balwani ("Balwani"). Specifically, your letter seeks access to six categories of documents, including communications, correspondence, notes, or recordings (hereinafter, "documents") relating generally to Theranos, Inc. ("Theranos") and (1) the Wall Street Journal and John Carreyrou, (2) Clinical Laboratory Improvement Amendment ("CLIA") compliance, (3) clinical laboratories, (4) FDA's determination of the type of approval required for Theranos' devices, (5) interviews with witnesses, and (6) the 2013 CLIA survey. Your request does not contain any date limitations.

As an initial matter, we do not expect FDA to have many responsive documents to categories (2) and (6), because the CLIA Program is implemented by the Centers for Medicare & Medicaid Services ("CMS"), not FDA. *See generally* 42 C.F.R. Part 493. Moreover, as you know, the Department of Justice ("DOJ") previously received from FDA and/or the Securities and Exchange Commission ("SEC") a significant number of FDA documents—over 40,000 pages—relating to Theranos, which DOJ has already provided to the Defendants. Def. Holmes Mot. to Compel, Dkt. #67, at 3 in *United States v. Holmes, et al.*; *see also id.* at 13 (describing DOJ's production of documents originally sourced from FDA as "substantial"); *see also* Def. Balwani's Joinder in Holmes Mot. to Compel, Dkt. #68. We also understand that DOJ has already provided to Defendants all of FDA's witness interviews related to this matter, which are responsive to category (5) of your request, and we do not expect that the agency will have additional documents to produce in this category.

As you also know, the Superseding Indictment against Defendants alleges wire fraud and conspiracy to commit wire fraud against doctors and Theranos' patients and investors.

FDA U.S. FOOD & DRUG ADMINISTRATION

Office of the Chief Counsel
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

The only allegation that mentions FDA states that Defendants "represented to investors that Theranos did not need [FDA] to approve its proprietary analyzer and tests, but instead that Theranos was applying for FDA approval voluntarily because it was the 'gold standard'; when, in truth, *[Defendants] knew that by late 2013 and throughout 2014, the FDA was requiring Theranos to apply for clearance or approval for its analyzer and tests*." Superseding Indictment, Dkt. #39, at 5, ¶ 12(F) (emphasis added). It seems, then, that the only documents that you are now requesting that are potentially relevant to this case are documents in category (4), which relate to what FDA told Defendants in late 2013 and throughout 2014 regarding the type of FDA approval or clearance required for Theranos' devices. Documents in the remaining categories are not relevant to the issues in your case.

Prior to receiving your letter, FDA was served with a subpoena (initially issued on September 12, 2018, and "reissued" on March 15, 2019) in *SEC v. Balwani*, Case No. 18-cv-01603-EJD (N.D. Cal.), the civil case brought by the SEC against Balwani. The subpoena requests 20 broad categories of documents referring or relating to Theranos, Holmes, and Balwani, from the 8½-year period from January 2010 through June 2018. The documents requested by your letter comprise a subset of the documents that are responsive to the subpoena.

To respond to the subpoena, FDA has already searched the records of at least 45 custodians, including both current and former FDA employees, and has collected in excess of 62,000 documents that contain the keywords for which we searched.[1] The agency is in the process of reviewing those documents for responsiveness and, for those that are responsive, conducting a page-by-page, line-by-line review for privilege and other protections, as more fully laid out below. **As we process the documents for the subpoena, we will provide documents to you, including those that are responsive to the six categories you have requested, with certain exceptions as set forth below.**

Please be aware that FDA does not currently have an automated method for identifying duplicates in the newly-collected documents, nor does it currently have an automated way to compare the newly-collected documents to the previously-produced documents. We are working with our information technology staff to make our review more efficient; however, at present, we need to manually compare the newly-collected documents to identify and remove duplicates, including lesser-included duplicates (such as a less complete email string). To the extent that FDA obtains an automated mechanism that would permit us to compare the newly-collected documents with the previously-produced documents, we will not re-produce any FDA documents already provided to Holmes and Balwani by DOJ.

[1] This is a document count, not a page count, and FDA has not completed inventorying all collected documents to count attachments separately. Accordingly, this number is an approximation of the minimum number of documents collected; the actual number likely will be significantly higher.

U.S. FOOD & DRUG ADMINISTRATION

Office of the Chief Counsel
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA also will not produce any automated emails sent to agency employees from public media or other organizations including, but not limited to, Bulletin Intelligence, GenomeWeb, The Gray Sheet, PharmaVOICE, POLITICO Pulse, and Google Alerts, which emails solely contain links to publicly-available information about Theranos. FDA will, however, provide any such emails that FDA employees forwarded with comment.

Before FDA can provide any documents in response to the subpoena and your request, we need to redact privileged and otherwise confidential information from the newly-collected documents. FDA is prohibited from releasing trade secret information obtained under certain of its regulatory authorities in judicial proceedings that are not brought under the Federal Food, Drug, and Cosmetic Act. 21 U.S.C. § 331(j). FDA is also prohibited from releasing trade secret and confidential commercial or financial information ("CCI") regarding certain devices obtained through the agency's regulatory and inspectional authorities. 21 U.S.C. § 360j(c). The Trade Secrets Act, 18 U.S.C. § 1905, also prohibits FDA from releasing trade secrets and CCI unless otherwise authorized by law. And, FDA regulations provide that trade secrets and CCI are not available for public disclosure. *See* 21 C.F.R. § 20.61. Many of the documents that are responsive to the subpoena and your request contain Theranos' trade secrets and CCI and may also contain third-party trade secrets and CCI. FDA cannot lawfully produce any responsive documents that would reveal such information absent a court order or a waiver permitting FDA to release such information in response to your request.[2] If the Theranos assignee provides a written waiver permitting FDA to release its trade secrets and CCI in response to the subpoena and your request, which we understand may be forthcoming, it would facilitate a quicker review and would result in the documents being less redacted and of more utility.

However, even if FDA receives a waiver from the Theranos assignee, the agency stills need to review and redact from the newly-collected documents third-party trade secrets and CCI, as well as privileged and otherwise-protected information, including attorney-client communications, attorney work product, personal privacy information, privileged investigatory files, privileged deliberative process, and/or other protected information. *See* 21 C.F.R. §§ 20.62–.67, 20.85. FDA will also redact all non-responsive information from the newly-collected documents. For example, there are documents from FDA's media staff that reference all open press inquiries and CDRH documents that reference all pending CDRH matters; FDA will redact as unresponsive all information unrelated to Theranos but will leave in any non-privileged information regarding Theranos.

In addition, because the subpoena and your request seek documents that have already been reviewed, redacted, and released publicly pursuant to the Freedom of Information

[2] To the extent DOJ and/or Defendants already possess FDA documents from which Theranos's trade secrets or CCI were not redacted, such productions were made pursuant to waivers from Theranos permitting FDA to provide the information to DOJ and SEC and permitting DOJ to give the FDA documents to the Defendants. To date, the Theranos assignee has not provided a waiver for FDA to release its trade secret and CCI in the newly-collected documents.

FDA U.S. FOOD & DRUG ADMINISTRATION

Office of the Chief Counsel
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Act ("FOIA") and for which subsequent review and redaction would constitute needless and/or burdensome duplication of time and effort, any responsive documents that have already been redacted will not be re-reviewed and, instead, will be provided as they were released to the public previously. Finally, FDA is limiting its search and production in response to your request to the time frame set forth in the subpoena, January 2010 through June 2018.

It will take a significant amount of FDA employee time to prepare and produce the documents responsive to the subpoena and your request. Although we cannot currently predict how much time it will take to review and process the newly-collected documents, we can begin producing documents to you on a rolling basis within one month.

FDA is committed to producing documents in a manner consistent with federal law and agency procedures. The agency has already expended a significant amount of resources to respond to document requests in connection with your criminal investigation of Defendants, SEC's civil investigation of Defendants, and Mr. Balwani's subpoena in the SEC civil action pending against him, and will continue to produce additional responsive, non-privileged documents consistent with the foregoing objections in response to your request.

If you have any further questions, please contact me at 301-796-8580.

Sincerely,

Marci B. Norton

Marci B. Norton
Senior Counsel

EXHIBIT D

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

CENTERS FOR MEDICARE & MED IC AID SERVICES

Center for Clinical Standards and Quality/ Quality, Safety & Oversight Group

June 10, 2019

John C. Bostic
Assistant United States Attorney
Northern District of California
150 Almaden Boulevard, Suite 900
San Jose, California 95113
John.Bostic@usdoj.gov

Re: Document Access Request - *United States v. Elizabeth Holmes and Ramesh Balwani*, 18-CR-00258 EJD

Dear Mr. Bostic:

This letter responds to your letter to me dated May 9, 2019 requesting access to certain categories of documents in connection with the above-referenced case. CMS has already expended significant resources to identify, search, collect, and produce over 260,000 pages to DOJ in this litigation and to respond to Mr. Balwani's September 14, 2018 subpoena in *SEC v. Balwani*, Case No. 18-cv-01602-EJD (SEC-Balwani Subpoena). The categories of documents you requested overlap significantly with DOJ's prior document requests during the investigation and with the categories of documents requested in the SEC-Balwani Subpoena. CMS is preparing a production in *SEC v. Balwani* pursuant to a May 30, 2019 Protective Order governing CMS productions in that matter. CMS can provide DOJ with a copy of the agency's production in the civil case once it is complete and after a Protective Order is entered in the criminal case.

To the extent your document requests seek CMS internal email, the agency is willing to produce responsive documents between September 1, 2013 and December 31, 2016 on the condition that an acceptable Protective Order is entered in the criminal matter. CMS does not construe DOJ's requests to include documents protected by the attorney-client or work product privileges and CMS does not plan to produce documents protected by those privileges.

CMS's response to each category of document requests is explained below.

1. **Any and all correspondence or communications regarding Theranos between the federal government and John Carreyrou, The Wall Street Journal, or their employees, agents, or counsel, and all government documents, communications, correspondence, notes, or recordings (including intra-agency and/or inter-agency correspondence) regarding same;**

CMS collected and reviewed external communications between CMS and the media about Theranos between September 1, 2013 and December 31, 2016 to respond to the SEC-Balwani Subpoena and is in the process of preparing a production of these documents. This effort

encompasses your request for communications between CMS and John Carreyrou and/or The Wall Street Journal. CMS will provide DOJ with a copy of the future civil production once it is complete and after a Protective Order is entered in the criminal matter.

CMS will identify, collect, review, and produce responsive internal communications after an adequate Protective Order is entered in the criminal matter.

2. **Any and all government documents, communications, correspondence, notes, or recordings (including intra-agency and/or inter-agency communications) regarding Theranos' Clinical Laboratory Improvement Amendments ("CLIA") compliance during the time period of the charged conspiracies, including but not limited to those that concern the 2015 CLIA survey of Theranos;**

CMS has already produced a large volume of documents responsive to this category of documents to DOJ, including, but not limited to, CMS CLIA group communications with Theranos, communications about meetings or calls with Theranos, documents and communications regarding Theranos's compliance with federal CLIA regulations, the CLIA surveys of the Theranos California and Arizona labs, CMS surveyor notes, CMS Form 2567s, Theranos's Plan of Correction and exhibits, and complaints CMS received about Theranos labs.

CMS identified, collected, and reviewed external communications between additional CMS custodians selected by Mr. Balwani and Theranos between September 1, 2013 and December 31, 2016 to respond to the SEC-Balwani Subpoena and is in the process of preparing a production. CMS will provide DOJ with a copy of the future civil production once it is complete and after a Protective Order is entered in the criminal matter.

CMS will identify, collect, review, and produce responsive internal communications after an adequate Protective Order is entered in the criminal matter.

3. **Any and all correspondence or communications regarding Theranos between the government and any clinical laboratory company or association affiliated with clinical laboratories (including but not limited to LabCorp, Quest Diagnostics, and the American Clinical Lab Association), or their employees, agents, or counsel, and all government documents, communications, correspondence, notes, or recordings (including intra-agency and/or inter-agency correspondence) regarding same;**

The CMS CLIA group does not generally communicate with third parties about the CLIA compliance of particular laboratories. The agency conducted a limited search for communications between the CMS CLIA group and LabCorp, Quest Diagnostics, or the American Association of Clinical Chemistry (AACC) to confirm this practice in response to the SEC-Balwani Subpoena. The search produced a few emails to or from AACC that are all form marketing emails or emails about attending the AACC Annual Scientific Meeting. CMS is in the process of preparing a production in the civil case that will include these documents and will provide DOJ with a copy once it is complete and after a Protective Order is entered in the criminal matter.

4. **Any and all government documents, communications, correspondence, notes, or recordings (including intra-agency and/or inter-agency communications) regarding the FDA's determination of the type of FDA approval required for Theranos' proprietary technology;**

CMS has few, if any, documents responsive to category four. Whether Theranos's proprietary technology required FDA approval was entirely an FDA determination. CMS already produced the few communications between the CMS CLIA group and the FDA about Theranos to Mr. Balwani in response to the SEC-Balwani Subpoena. CMS will provide a copy of this production to DOJ.

CMS also conducted a search for communications between additional CMS custodians selected by Mr. Balwani and the FDA during the time period September 1, 2013 to December 31, 2016 to complete its response to the SEC-Balwani Subpoena. CMS is currently reviewing the search results for responsive, non-privileged documents and plans to include these documents in the future production in the civil case. CMS will provide DOJ with a copy of that future production once it is complete and after a Protective Order is entered in the criminal matter.

5. **Any and all FBI 302s or other agency ROIs memorializing government communications with witnesses, and all government documents, communications, correspondence, notes, or recordings (including intra-agency and/or inter-agency correspondence) regarding same; and**

CMS does not have documents responsive to category five.

6. **Any and all government documents, communications, correspondence, notes, or recordings (including intra-agency and/or inter-agency communications) regarding the 2013 CLIA survey of Theranos.**

CMS already produced to DOJ the relevant documents pertaining to the 2013 Theranos CLIA survey that CMS could pull from its system.

The 2013 Theranos CLIA survey was a routine survey performed by California Department of Public Health's California Laboratory Field Services (CDPH). State agencies do not usually communicate with CMS when performing routine CLIA surveys. The CMS CLIA group is not aware of any email communication with CDPH about the 2013 survey.

CMS will identify, collect, review, and produce responsive internal communications after an adequate Protective Order is entered in the criminal matter.

CDPH has located eight documents related to the federal 2013 Theranos CLIA Survey. The CDPH surveyor notes from the 2013 survey are no longer available. CDPH is not aware of any internal communications or written communications with CMS regarding the 2013 Theranos CLIA survey. *See* Attachment A, Declaration of Donna McCallum, June 3, 2019. These documents will be included in the production CMS is preparing in response to the SEC-Balwani Subpoena. CMS will provide DOJ with a copy of that future production once it is complete and after a Protective Order is entered in the criminal matter.

CMS is committed to working with you to produce documents responsive to your requests as detailed above. Please contact CMS counsel to discuss this matter further.

Sincerely,

Karen W. Dyer

Karen W. Dyer
Director
Division of Clinical Laboratory Improvement and Quality
Centers for Medicare & Medicaid Services

EXHIBIT E

DECLARATION

I, Donna McCallum, hereby declare under penalty of perjury under the laws of the State of California that the following statements are true to the best of my knowledge and belief:

1. I am the Section Chief for the Clinical Laboratory Improvement Amendment (CLIA) Section for the California Department of Public Health's Laboratory Field Services (LFS). I have knowledge of the facts stated herein.
2. The mission of LFS is to ensure quality standards in clinical and public health laboratories through certification, examination, inspection, education and proficiency testing. Among other things, LFS is responsible for the enforcement of state and federal laws governing clinical laboratories in the State of California.
3. Federal Centers for Medicare and Medicaid services (CMS) documents in the custody of LFS regarding the 2013 CLIA survey of Theranos consist of the following:
    a. Survey Tracking Form
    b. Form CMS-1539
    c. Form CMS-209
    d. Form CMS-1557
    e. Theranos Updated Form CMS-2567, dated 1/17/13
    f. Form CMS-670
    g. Notice of Standard-Level Deficiencies, dated 12/10/13
    h. Form CMS-116
4. To my knowledge, notes from the LFS CLIA Section surveyor's 2013 routine CLIA survey of Theranos are no longer available.
5. To my knowledge, there are no internal communications or written communications with CMS regarding the 2013 CLIA survey as it was a routine survey.
6. LFS has initiated an email search to verify that no email communications with CMS regarding the routine 2013 CLIA survey of Theranos exist and will confirm with CMS once the search inquiry is completed.

I declare under penalty of perjury that the foregoing is true and correct.

Donna McCallum
Declarant Signature

6/3/2019
Date

EXHIBIT F

THOMAS T. HWANG
TELEPHONE: (650) 843-2757
FACSIMILE: (650) 857-1288
EMAIL: HWANG.THOMAS@DORSEY.COM

June 11, 2019

Via First Class Mail and Email: lauren.dipaola@fda.hhs.gov; Marci.Norton@fda.hhs.gov
U.S. Food and Drug Administration
Office of Regulatory Affairs
12420 Parklawn Drive
Element Bldg., Rm. 4042
Rockville, Maryland 20857
Attn: Lauren DiPaola
Attn: Marci Norton

Re: *Securities and Exchange Commission v. Balwani*;
Case No. 18-CV-01603-EJD

Dear Ms. DiPaola and Ms. Norton:

As you are aware, my firm represents Theranos (Assignment for the Benefit of Creditors) LLC, the assignee ("Assignee") of Theranos, Inc. ("Theranos"), pursuant to the general assignment for the benefit of creditors under California law.

We write to confirm that the Assignee grants the U.S. Food and Drug Administration (the "FDA") and the Centers for Medicare and Medicaid Services ("CMS") permission to release, subject to and solely in accordance with the terms of that certain *Supplemental Stipulated Protective Order Regarding FDA Or CMS Information* [Dkt No. 83], materials which were provided by Theranos to the FDA/CMS and marked as confidential or which otherwise contain Theranos' trade secrets or confidential commercial information, to the Securities and Exchange Commission ("SEC") and Defendant Ramesh Balwani, in response to the SEC's request or to subpoenas issued in the above-referenced matter, provided that all materials are marked

Lauren DiPaola
Marci Norton
U.S. Food and Drug Administration
Office of Regulatory Affairs (ORA)
June 11, 2019

"FDA/CMS – CONFIDENTIAL." The Assignee does not consent to production of the materials for use in any other matter, nor to any disclosure pursuant to a Freedom of Information Act request.

Very truly yours,

DORSEY & WHITNEY LLP

By 
Thomas T. Hwang

cc: Assignee
Steve Cazares (*via email*: stevecazares@dwt.com)